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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,703	06/27/2000	Markus Pompejus	BGI-129CP	3829

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EXAMINER
MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/605,703	Applicant(s) POMPEJUS ET AL.	
	Examiner Marjorie Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/30/02 received 06/04/02 in the USPTO* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-62* is/are pending in the application.

4a) Of the above claim(s) *62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

El ction/Restrictions

Applicant's election with traverse of Group I in Paper No. 11, filed 5/30/2002 is acknowledged. The traversal is on the ground(s) that Groups I-III recite the same nucleic acid sequences. As the claims of Groups I-III have been cancelled, and new claims 39-61 appear to recite the same set of nucleic acid sequences, this argument is moot. Elected Group I and new claims 39-61 appear to be drawn to the same nucleic acid sequences, vectors and host cells, therefore claims 39-61 are considered elected. Applicant also argues that Group IV should be considered elected as it is drawn to a method of use of the nucleic acid of Group I (i.e. the elected nucleic acids). This is not found persuasive because claim 62 is drawn to a method of producing a polypeptide, wherein the polypeptide is not limited to be the one expressed by the elected nucleotide sequence. It is admitted that claim 62 recites use of a host cell comprising the elected nucleic acid sequence; however, the host cell and/or nucleic acid may be used in a variety of other methods of use, including replication and purification of the nucleic acid itself (use of the host cell), and uses in methods of hybridization (the nucleic acid). For these reasons, the examiner maintains that the method of use recited in new claim 62 is separate and distinct from new claims 39-61, therefore claim 62 is not considered elected. Applicant did not traverse the election of species requirement. With regard to the requirement for election of a single sequence, applicant cites the MPEP and OG notice wherein the requirements of 37 CFR 1.141 were waived. As set forth in the restriction requirement, and copied onto page 2 of applicants "Remarks" in the response filed 5/30/02, "Due to the increasingly large size of sequence databases which must be searched and the increasing numbers of applications requiring sequence searches, it creates an undue burden on the Office to search more than a single sequence (product) per application. For these reasons, *the requirements of 37 CFR 1.141 et seq. are no longer waived* ." With regard to arguments that is would not be an undue

burden to search and examiner more than a single sequence, it is noted that a search for any sequence requires a search of nonpatent literature and foreign patents as well as US patents, therefore the examiner maintains that it would be an undue burden to search and examiner more than one sequence. In response to the argument that the sequence restriction be treated as a species election, it is noted that each sequence represents a different structure; i.e. product, and therefore each sequence is a different invention. For the reasons set forth above, the examiner maintains that the requirement for election of a single sequence is a proper restriction requirement, and maintains the requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claim 62 and all SEQ ID NO's other than SEQ ID NO: 1 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

An action on the merits of elected claims 39-61, as they read on elected SEQ ID NO: 1, follows.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 54. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant is thanked for providing supplemental copies of Appendices A and B. It is noted that Appendices A and B do not comply with the sequence rules, specifically 37 CFR

1.821 (d). The specification is therefore objected to for not being in compliance with the sequence rules. As the claims recite SEQ ID NO's, and for purposes of compact prosecution and pendancy reduction, an office action on the merits of the claims follows. However, applicant is advised that all sequence rules must be complied with at the time of filing of any reply to this office action in order for that reply to be considered responsive.

35 U.S.C. 112, Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39, 43-45, 47, and 49-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK of WRITTEN DECRITPION rejection.

The specification discloses SEQ ID NO: 1. Sequences consisting of SEQ ID NO: 1 meet the written description provisions of 35 USC 112, first paragraph. However, claims 39, 45, 47, 49, and 54-55 recite open claim language (comprising) and are therefore directed to encompass gene sequences, sequences that hybridize to SEQ ID NO: 1, corresponding sequences from other species, mutated sequences, and sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. It is noted that claims 45 and 47 specifically recite homology limitations, and claim 49 is drawn to a fragment of a nucleic acid. A nucleotide sequence which is 50% different from SEQ ID NO: 1 is a different structure than SEQ ID NO: 1, and would be expected to have different properties (e.g. may encode a different protein or may not encode a peptide at all). The specification does not describe sequences or

structures which are 50% different from SEQ ID NO: 1 nor does it disclose any properties of compounds which are 50% different from SEQ ID NO: 1, which would allow one skilled in the art to envision the structures, sequences or compounds encompassed by the claims. A nucleic acid comprising a fragment of SEQ ID NO: 1 may also comprise a vast variety of other nucleotides, any of which would be expected to have different properties than that of SEQ ID NO: 1. See the rejections under 35 USC 102, below. The instant specification does not, for example, describe a gene encoding an LDL receptor.

Claims 43-44, 50-53 are directed to nucleic acids encoding polypeptides which are et least 50% identical to recited SEQ ID NO's. The specification discloses that SEQ ID NO: 2 is one polypeptide sequence encoded by SEQ ID NO: 1; however SEQ ID NO: 1 comprises several possible start codons, and may therefore encode several different polypeptides. See below. A polypeptide which does not consist of the entirety of SEQ ID NO: 2 may be encoded by any number and variety of polynucleotide sequences, none of which would necessarily be the same as or similar to SEQ ID NO: 1. The specification does not disclose polypeptide with any degree of identity less than 100% to SEQ ID NO: 2 nor does the specification disclose any polynucleotides encoding a polypeptide with identity to SEQ ID NO: 2 which is less than 100%. It is noted that the specification does not necessarily have to disclose every possible embodiment of a claim. However in the instant case, the specification fails to describe any specific embodiment of a polypeptide encoded by elected SEQ ID NO: 1 which is less than 100% identical to SEQ ID NO: 2, for example, and fails to describe any specific embodiment of a polynucleotide which encodes a polypeptide which is less than 100% identical to SEQ ID NO;2, and it is clear that a vast number and variety of nucleic acids are encompassed by the claims, therefore the specification fails to fully and completely describe the genus of sequences embodied by the claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the

complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only sequences consisting of SEQ ID NO: 1, and sequences which encode a polypeptide consisting of SEQ ID NO: 2, but not the full breadth of the claims, meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claims 43, 44, 47, 48, 52, 53-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a LACK of WRITTEN DESCRIPTION rejection.

A nucleotide sequence comprising or consisting of SEQ ID NO: 1, or a portion thereof, which encodes an MCP polypeptide and/or a polypeptide capable of modulating the production of a fine chemical, are not described by the instant specification. The specification discloses in Table 1 that SEQ ID NO: 1 encodes SEQ ID NO: 2, which is a polypeptide. The specification further discloses on pages 21-22 that the inventive nucleic acid molecule encodes an amino acid sequence "sufficiently homologous" to an amino acid sequence of Appendix B such that the protein or portion thereof which is encoded maintains the ability to modulate yield, production, etc. of a fine chemical. None of the sequences shown in Appendix B are identified by SEQ ID NO. However, Table 1 discloses that SEQ ID NO's 1 and 2 are identified as RXN01638, on page 1 of the Table. Appendix B lists a sequence labeled RXN01638, on page 64, which appears to match SEQ ID NO: 2, therefore Appendix B does appear to list the entirety of SEQ ID NO: 2. Appendix B does not appear to list any "portions" or fragments of SEQ ID NO: 2. In

addition, Appendix B is merely a listing of amino acid sequences, and contains no information with regard to activity of the peptides represented.

Although applicant was clearly in possession of SEQ ID NO: 2 at the time of filing, the specification does not teach anywhere whether SEQ ID NO: 2, or any other peptide encoded by SEQ ID NO: 1 actually has the activity recited in the instant claims. The specification teaches, on pages 51-52, prophetic examples for how to determine the activity, and potential use for production of fine chemicals, of mutant proteins, but does not disclose whether SEQ ID NO:2 is one of the "mutant proteins" to be so tested, nor whether SEQ ID NO: 2 is actually known to have ANY activity, specifically one which modulates the production of fine chemicals. SEQ ID NO: 1 has several potential start codons, and therefore may encode polypeptides or proteins other than SEQ ID NO: 2. If so, these peptides are not disclosed by the instant specification, nor does the instant specification disclose whether any activity is known for peptides other than SEQ ID NO: 2 which may be encoded by SEQ ID NO: 1. As the instant specification does not teach that SEQ ID NO: 2, or any portion thereof, or any other peptide encoded by SEQ ID NO: 1 was known at the time of filing to have MCP activity and/or activity in modulating the production of fine chemicals, the claims are rejected for lack of written description.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-42, 45-49, and 54-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 39-42 and 45-49 recite the phrase "or a complement thereof" with regard to a nucleic acid molecule . The term "complement" is not defined by the specification and may have several meanings in the art; e.g. a sequence which is partially complementary to, a sequence which is fully complementary to, or a sequence with a specified degree or percentage of complementarity to the elected SEQ ID NO: As the metes and bounds intended by applicant for a "complement" are unclear, the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 49 is rejected under 35 U.S.C. 102(b) as being anticipated by SAITO et al. (US 5,665,872).

SAITO teaches SEQ ID NO's 5 and 6 (col's 39-62), each of which encodes an LDL receptor protein and comprises a fragment of 22 contiguous nucleotides which are 100% identical to residues 165-186 of instant SEQ ID NO: 1, thus anticipating claim 49.

Claim 49 is rejected under 35 U.S.C. 102(b) as being anticipated by MICHAELS et al. (US 5,554,534).

MICHAELS teaches SEQ ID NO: 3 (col's 27-30), which comprises a fragment of 20 contiguous nucleotides which is 100% identical to residues 489-508 of instant SEQ ID NO: 1, thus anticipating claim 49.

Conclusion

No claims are allowed; the specification is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a patent analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

Marjorie A. Moran
Examiner
Art Unit 1631

August 22, 2002